COCA Now

CDC Clinician Outreach and Communication Activity

July 22, 2022

New Streamlined Process to Provide Tecovirimat (TPOXX) for Treatment of Monkeypox

Revised, simplified protocol reduces data collection and reporting requirements making it easier for clinicians

CDC, in partnership with FDA, has made it easier for healthcare providers to provide tecovirimat (TPOXX) treatment to patients with monkeypox under an expanded access Investigational New Drug (EA-IND) protocol. The streamlined process reduces the number of required forms, patient samples, and photos, and gives patients the option to see their doctor virtually.

The changes in the revised TPOXX EA-IND protocol include:

- Reduced number of case report forms from 6 forms (17 pages) to 2 forms (6 pages)
- Changed all patient assessments to virtual (via telemedicine) or in-person
- Reduced required assessment and follow-up visit to 3 time points that could be done via telemedicine visits.
    - Patients would be assessed prior to treatment, once during the 14-day therapy, and once after completion of treatment.
- No longer require photos of lesions
- All laboratory sample testing and monitoring parameters are optional with suggestions on when to consider performing them. For example:
    - Pharmacokinetic and serum samples are no longer required.
    - Clinical laboratory parameters (hematology, chemistry, and urinalysis parameters) are no longer required
- Required safety reporting by clinicians and healthcare facilities will focus on serious adverse events only and should be reported by filling out a MedWatch form and returning to CDC via email (regaffairs@cdc.gov)
- Added clarification on syringe pumps for IV infusions and duration of infusion.
- Clinicians can **start treatment** upon obtaining informed consent. All paperwork can be completed and submitted after starting treatment.

CDC is committed to ensuring that healthcare providers are able to easily access TPOXX for patient care.

For more information, see CDC's website on Obtaining and Using TPOXX (Tecovirimat).

The Emergency Risk Communication Branch in the Division of Emergency Operations, Center for Preparedness and Response is responsible for the management of all COCA Products.

For information about this update or other clinical issues, or to send your feedback, please contact us at coca@cdc.gov
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Crisis & Emergency Risk Communication Training—training program that draws from lessons learned during public health emergencies, and incorporates best practices from the fields of risk and crisis communication
Health Alert Network—CDC's primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories

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